

DRAFT FOR PUBLIC COMMENT

January 22, 2003

JUSTIFICATION STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. Identification of the Information Collection

- 1(a) Title of the Information Collection: APPLICATION FOR EXPERIMENTAL USE PERMIT (EUP) TO SHIP AND USE A PESTICIDE FOR EXPERIMENTAL PURPOSES ONLY

OMB NO.: 2070-0040

EPA NO.: 0276.12

1(b) Short Characterization/Abstract

This information collection program provides the EPA with the data necessary to determine whether to issue an experimental use permit under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. FIFRA requires that before a pesticide product may be distributed or sold in the U.S. it must be registered by EPA. However, section 5 authorizes EPA to issue experimental use permits which allow pesticide companies to temporarily ship pesticide products for experimental use for the purpose of gathering data necessary to support the application for registration of a pesticide product. In general, EUP's are either issued for a pesticide not registered with the Agency or for a registered pesticide for a use not registered with the Agency.

The information collected and reported under an EUP is a summary of that which is routinely submitted in connection with registration. The EUP allows for large scale field testing, if necessary, in order to collect sufficient data to support registration. An EUP is not required if the person conducting the tests does not expect to receive benefits in pest control.

EPA Form 8570-17, Application For An Experimental Use Permit To Ship And Use A Pesticide For Experimental Purposes Only, is filed by the prospective registrant for a permit to generate information or data necessary to register a pesticide under Section 3 of FIFRA, (see Attachment C). This information from the applicant is necessary in order to grant and effectively monitor the EUP. Beyond the information as supplied on EPA Form 8570-17, is a final report on the results of the experimental program which includes information such as: amount of the product applied; the crops or sites treated; any observed adverse effects; any adverse weather conditions which may have inhibited the program; the goals achieved; and the disposition of containers, unused pesticide material, and affected food/feed commodities.

DRAFT FOR PUBLIC COMMENT

January 22, 2003

If the food/feed treated under the terms of an experimental use permitted are to be shipped in commerce, the applicant must also submit a petition for temporary tolerance pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). This program is more fully described in ICR No. 2070-0024 "Tolerance Petitions for Pesticides and Inert Ingredients on Food/Feed, EPA No. 0597.

2. Need for and Use of the Collection

2(a). Need/Authority for the Collection

As required by section 5 of FIFRA, (see Attachment A), and Part 172 of Title 40 of the Code of Federal Regulations (40 CFR Part 172), the information collected and reported is necessary to evaluate the potential hazard of the product and to make certain that the permit was issued for genuine experimental purposes rather than as a form of temporary registration. To ensure compliance, the final report is compared with the objectives of the testing program. The information also enables EPA to identify whether the treated food or feed crops will be used in a commercial market which would require issuance of a temporary tolerance or destroyed because the use was for research purposes only. Since it is common for applicants to request extensions of EUP's, it is imperative that the Agency has reports in hand in order to judge the need for such extensions.

Exemptions from EUP requirements:

Under the existing EUP regulations, small-scale experimental uses of pesticides are presumed exempt from the EUP requirements. EPA will not require an EUP for a substance or mixture of substances being put through laboratory or greenhouse tests, or fewer than one surface acre per pest for terrestrial tests or fewer than ten acres per pest for aquatic tests, in which the sole purpose under the following small scale field testing scenarios:

Land-Pesticide testing on plots of land ten acres or less in size:

Specifically, test plots may be as large as ten acres per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the test plot may not exceed ten acres in size. Furthermore, any food or feed crops involved in or affected by the tests must be destroyed or consumed only by experimental animals unless a tolerance or exemption from a tolerance has been established.

Aquatic Uses-Pesticide testing on water bodies one surface acre or less in size:

DRAFT FOR PUBLIC COMMENT

January 22, 2003

Specifically, water bodies may be as large as one acre per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the water body may not exceed one acre in size. Bodies of water involved in or affected by the tests may not be used for irrigation, drinking water supplies, or body contact through recreational activities. In addition, pesticides may not be tested in waters that contain or affect any fish, shellfish or other plants or animals which may be taken for food or feed unless a tolerance or exemption from tolerance exists for the test product.

Animal Treatment Uses:

Tests may be conducted only in cases where experimental animals will not be used for food or feed unless a tolerance or exemption from tolerance exists for the test product.

Other Uses:

For testing operation for which acreage limits do not accurately reflect whether the testing is to be considered small-or large-scale, the Agency will determine on a case-by-case basis whether an exemption from the requirement from an EUP is appropriate.

The exemptions described above are not definitive, 40 CFR 172.3 gives EPA discretionary authority to exempt particular testing operations from the EUP requirements under other conditions. 40 CFR 172.3 also allows EPA discretionary authority to require EUP's for testing operations even when the exemption conditions of 40 CFR 172.3(b) and (c) are met.

EUPs for Small-scale Field Testing of Microbial Pesticides:

Because of concern about the potential for microorganisms to reproduce and multiply in the environment and the potential for these microbials to cause unforeseen adverse impacts, the Agency may require an EUP for small scale field testing of certain novel microbial pesticides (i.e., genetically-altered and non-indigenous microbial pest control agents). Prior to the initiation of any small scale field testing involving genetically-altered or non-indigenous microbial pest control agents, the research organization, company, or individual must submit a notification to the Agency so that a determination can be made as to whether an EUP is required. 40 CFR 172.43-59 present the requirements for an EUP for field testing of microbial pesticides. Note that these differ significantly from the EUP requirements for testing other pesticides.

2(b). Practical Utility/Users of the Data

The information collected and reported under an EUP will enable the Agency to:

DRAFT FOR PUBLIC COMMENT

January 22, 2003

- judge whether a renewal, extension or amendment of the EUP, if requested, is justified;
- allow for adequate monitoring of the EUP program; and
- ascertain the cause/effect relationship when a pesticide is registered and later found to have adverse effects (as in the case of phytotoxicity).

Efficacy data are also furnished to the Agency when products being tested are important to public health; such as products to control microorganisms infectious to man and vertebrates that may transmit diseases to humans.

3. Non duplication, Consultations, and Other Collection Criteria

3(a). Non duplication

The respondent is not required to submit any sort of EUP-related information or data to any other Federal agency or to any other EPA program offices. FIFRA section 7 (Attachment B), however, does require annual pesticide production reports from all persons who produce pesticides. The pesticide material produced in conjunction with an EUP would be included in these annual production reports; however, annual production information is not required as a condition of the EUP, only total production in the final report.

3(b). Consultations

Consultation and/or dialogue between the respondent and EPA occurs on an informal, ongoing "as needed" basis, primarily during the submission and review of the application for an experimental use permit. The experience has been that if any sort of problem, such as technical, administrative, or otherwise arises, the respondent is given ample opportunity to inform the agency and vice versa. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not necessarily by a prescribed schedule.

3(c). Effects of Less Frequent Collection

There is only one submission required in conjunction with each request for EPA approval to conduct testing on certain pesticides. Therefore, the frequency of the collection cannot be reduced, except to eliminate the collection altogether. The Agency then would have no means by which to evaluate the potential human health risks and environmental hazard presented by a proposed test.

3(d). General Guidelines

DRAFT FOR PUBLIC COMMENT

January 22, 2003

The only guideline under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the manufacturer remains in business. Pesticide registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical, or tax records not be required to be retained for more than three years will be exceeded in this program.

3(e). Confidentiality and Sensitive Questions

(i) Confidentiality

When trade secret information or Confidential Business Information (CBI) is provided to the Agency, such information is protected from disclosure under FIFRA Section 10, as amended and EPA's confidentiality regulation, Title 40 CFR, Subpart B). Data submitted to the Agency are handled strictly in accordance with the FIFRA CBI Security Manual. This manual contains instructions relative to all contact with confidential documents, including responsibility of EPA employees; physical security measures; CBI materials within EPA, such as CBI typing procedures (documents typed internally or on contract); and division internal procedures. The manual dictates that: (1) all CBI must be marked or flagged as such, (2) all CBI must be kept in secure (double-locked areas, and (3) all CBI for destruction must be cleared by a document control officer and placed in the Office of Prevention, Pesticides and Toxic Substances paper shredder.

(ii) Sensitive questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

4. The Respondents and the Information Requested

4(a). Respondents/NAICS Codes

The North American Industrial Classification System (NAICS) code for is 325320 (Pesticide and other Agricultural Chemical Manufacturing).

4(b). Information Requested

(I) Data Items

DRAFT FOR PUBLIC COMMENT

January 22, 2003

Standardized Form 8570-17 must be submitted to EPA with each EUP application. The type of information to be submitted with the application depends on whether the product is already registered and whether a tolerance is required for the testing covered under the EUP. 40 CFR 172.4 lists the information required in each case.

An application for an EUP may be submitted by any company or person wishing to generate the information necessary as required by section 3 of FIFRA in accordance with the regulations found in 40 CFR 172.2(a). The applicant may be a potential registrant, an independent researcher or testing laboratory, or any similar agent or consultant of a manufacturer. Applications must be submitted to the following address:

Document Processing Desk (EUP)
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Information Required in All EUP Applications

Each EUP application must contain the following information together with a completed copy of Standardized Form 8570-17:

- Applicant's name and address;
- The registration number of the product, if it has been registered (information requirements for unregistered products are listed below in a separate section);
- Purpose or objectives of the proposed testing;
- Detailed description of the proposed testing program including the following test parameters:
 - Pest organism(s) involved;
 - Amount of pesticide proposed to be used;
 - Crops, fauna, and flora involved;
 - Sites and modes of pesticide applications;
 - Pesticide dosage rates;
 - Location of test site, including States;
 - Number of acres in test site;
 - Number of structural sites or number of animals by State to be included in the testing;
 - Proposed dates of the testing; and
 - How the testing will be supervised.

DRAFT FOR PUBLIC COMMENT

January 22, 2003

- Name, street address, telephone number and qualifications of program participants, including those not employed by the applicant;
- Names and street addresses of cooperators (persons owning or controlling application sites and granting permission to permittees to use these sites);
- Results of prior testing of product by applicant to determine:
 - toxicity and effects in or on target organisms;
- toxicity and effects in or on nontarget plants, animals and insects at or near the application site; and
- adverse effects to the environment from application of this product; and
- How the applicant intends to store and dispose of unused pesticide and containers from the proposed experimental use.

Information Required When the Product to be Tested is Not Already Registered

In addition to the information listed immediately above, when the product to be tested has not been registered, the applicant must provide the following information:

- A complete confidential statement of composition giving the composition of the formulation to be tested as a tabulation of the names and percentage by weight of each ingredient, both active and inert;
- Chemical and physical properties of each active ingredient of the formulation being tested including the analytical methods to be used to determine these;
- available data on the rate of decline of residues on the treated crop or site together with other information relevant to determining when workers can safely re-enter treated areas; and
- Available toxicity and exposure data, including human epidemiological data, relevant to assessing the potential of the product to cause injury to users and other people who may be exposed.

When Testing May Result in Pesticide Residue on Food

When the product to be tested is to be used in such a manner to leave residue on food or feed, the applicant has three options for determining that treated crops are not used for food or feed use without a tolerance:

- The applicant may submit evidence that a tolerance or a tolerance requirement exemption has been established under Section 408 of the Federal Food, Drug and Cosmetic Act;
- The applicant may submit a petition for a new tolerance or for an exemption from the requirement for a tolerance established under Section 408 of the Federal Food, Drug and

DRAFT FOR PUBLIC COMMENT

January 22, 2003

Cosmetic Act (FFDCA) (Chapter 7 of this document, Tolerance Petitions, describes this process in detail); and

- The applicant may certify that the food or feed derived from the experimental program will be destroyed or will be fed only to experimental animals which will be destroyed. Alternatively, the applicant may certify that the food or feed derived from the experimental program will be disposed of in another manner which does not endanger man or the environment; the permit application shall specify the means of such disposal.

EUP applications should be submitted to EPA as far in advance as possible of the first shipping date, at least six months in advance. FIFRA section 5(a) requires EPA to complete EUP reviews within 120 days, and failure to provide the appropriate information or data may delay processing of the EUP beyond this date.

Labeling Requirements

All pesticides shipped or used under an experimental use permit must be labeled with directions and conditions for use including the following:

- The prominent statement “For Experimental Use Only;”
- The Experimental Use Permit Number;
- The statement “Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program”;
- The name, brand or trademark;
- The name and address of the permittee, producer, or registrant;
- The net contents;
- An ingredient statement;
- Warning or caution statements;
- Any limitations on entry of persons into treated areas;
- The establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and
- The directions for trial use.

Extensions or renewal of Experimental Use Permits

EUPs and associated temporary tolerances are usually issued for a period of one or two years. The permit and any associated temporary tolerances, may be extended, renewed, or amended upon written request to the Agency, if circumstances warrant.

Fee Requirements

DRAFT FOR PUBLIC COMMENT

January 22, 2003

If an application for an EUP is accompanied by a petition for a tolerance, temporary tolerance, an exemption from the requirement of a tolerance, or a temporary tolerance exemption, the petition is subject to fee requirements that are addressed in Chapters 7 and 8 of the EPA “Bluebook”. An extension or renewal request for a temporary tolerance is also subject to a fee requirement.

Use of an EUP Product on Food or Feed Crops

A product may only be used on food or feed crops if the Agency has issued tolerances or exemptions from requirements for tolerances for all inert ingredients, metabolites, and degradation products, as well as active ingredients. If the proposed labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, applicants must submit a statement indicating whether a tolerance or an exemption from the requirement of a tolerance has been issued by the Agency under section 408 of the Federal Food Drug and Cosmetic Act (FFDCA).

If a tolerance, exemption from the requirement of a tolerance has not been issued for such residues, applicants must include with the application a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulation in accordance with 40 CFR 180. Alternatively, applicants may certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment.

Suggested Format for an Experimental Use Permit Application

The following format is an example of an acceptable EUP application. Please note that all of the items are not necessary in every case. Depending on whether the product being tested is already registered with EPA, and whether a tolerance is necessary because treated crops will be used as food or feed, several of these entries may not be necessary.

Section A

This section should include a data sheet detailing the chemical and physical properties of the test chemical along with a complete statement of the names and percentages by weight of each active and inert ingredient in the formulation to be shipped.

Section B

This section should include a copy of the proposed experimental label. The minimum labeling requirements are set forth in 40 CFR 172.6.

DRAFT FOR PUBLIC COMMENT

January 22, 2003

Section C

This section should include toxicity data, including LD₅₀ values, eye and skin irritation data for the formulated product, and subacute, teratology (one species), mutagenicity, and possibly chronic and reproduction data on the active ingredient. Data on the product's toxicity to fish and wildlife may also be included in Section C as appropriate.

Section D

This section should include residue data, including when appropriate, data on: (1) food or feed commodities; (2) non-food crops such as tobacco; or (3) foliage or other sites where the product may be used and on which remaining residues of the product may pose a risk to man or the environment. Section D also includes a description of the analytical methods used, a summary of the residue data acquired, and when appropriate, environmental fate data.

Section E

This section should include product performance information demonstrating that the product is useful for the purposes proposed. Because EPA has waived the requirement for submitting efficacy data for all products except those with public health uses, Section E need not contain actual efficacy data, but should include a summary of the results of all efficacy testing performed on the product.

Section F

This section should include a statement explaining whether a tolerance exists or is being requested, especially if the product is to be tested in a manner that may result in residues in food or feed. If a tolerance is being requested, the temporary tolerance petition must be provided with the EUP application. Whenever all food or feed derived from the experimental program is to be destroyed or fed to experimental animals, a statement must be included explaining this.

Section G

The section should include details concerning the proposed experimental program, including:

- qualifications, names, addresses and telephone numbers of all EUP participants, including cooperators, i.e., persons who grant permission for an experimental use pesticide to be used on application sites which they own or control;

DRAFT FOR PUBLIC COMMENT

January 22, 2003

- names of states in which the product will be used, along with the amount of active ingredient and acreage (or other appropriate measures) to be used in each state, and the names of states in which the pesticide may be shipped for further distribution;
- details of the proposed EUP program, including types of pests or organisms targeted; the crops animals, surface, or sites to be treated; the geographical areas where the material is to be used; the use patterns, intended plot sizes, number of plots, number of replicates, and other test parameters to be used;
- information on prior testing, including a description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine, toxicity and effects in or on any target organisms at the site of application; phytotoxicity and other forms of toxicity or effects on nontarget plants, animals and insects, at or near the site of application; or any adverse effects on the environment;
- objectives of the EUP program, including a statement specifying the type of data to be collected and the intended gain from conducting the program;
- justification for the quantity (volume) of active ingredient proposed to be used under the EUP, including a statement specifying the various parameters used to determine the quantity of active ingredient;
- a statement proposing a suitable duration for the EUP commensurate with the program objectives; and
- details concerning the method of disposing of unused materials at the conclusion of the testing program.

Program Surveillance and Data Reporting Requirements for an Experimental Use Permit

Once the permit is issued and the pesticide testing is underway, the applicant is required to track the results at each test site and submit a final report to EPA which shall include (40 CFR 172.8):

- All data gathered during the testing program. Although field notes need not be included in this report, they must be kept available for EPA review upon request.
- A report of how pesticide containers and unused pesticides were disposed of, including the quantity disposed of, disposal sites and disposal methods.

DRAFT FOR PUBLIC COMMENT

January 22, 2003

- In the case where meat-producing animals or birds are treated by or exposed to an experimental use pesticide, the applicant must report the name and location where the animals will be processed to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC, 20250.
- The applicant must also report any adverse effects from use of or from exposure to the pesticide being tested.

EPA may require advance notice from the applicant of the intended test dates, sites and times. The applicant must also allow EPA access to the testing site to determine whether the testing complies with the terms and conditions of the permit.

(ii) Respondent Activities

The following are the activities to be conducted by a representative respondent (applicant) in order to comply with the provisions of EPA Form 8570-17.

Activity	Explanation
read FIFRA Section 5 and 40 CFR 172.8(b)	become familiar with the legislation and regulations and determine the requirements as they pertain to a proposed experimental use of a pesticide
plan activities	plan the actions necessary to comply with the legislation and regulations
create information	develop information required for notification
gather information	gather information required for the notification or containment records
process, compile, and review information	check information for accuracy and completeness
complete paperwork	prepare notification document or containment record
record, disclose, and display information	submit notification to OPP
store, maintain, and file information	retain copies of all submissions

DRAFT FOR PUBLIC COMMENT

January 22, 2003

5. The Information Collected–Agency Activities, Collection Methodology, and Information Management

5(a). Agency Activities

The following are activities necessary to evaluate a submitted request for an experimental use permit:

Activity	Explanation
review submitted application package	review application form and package for completeness and appropriateness
record submission	record submission in tracking system
analyze submission	conduct scientific reviews of data
file submission	store and maintain submission information in Agency files system

5(b). Collection Methodology and Management

A submitted EUP package usually includes three parts: an EPA Application Form 8570-17, the product label, and, in most cases, supporting data. The application form and the product label are pin-punched by date by the Front-End Application Processing Unit for initial screening. If everything is found to be complete, the proposed EUP is given a file symbol, entered into the appropriate tracking system, and a registration jacket is created identifying the document by the appropriate Product Manager (PM) for the chemical being employed. The accompanying data is identified and processed for review.

The three-part EUP package is sent to the designated PM who is responsible for managing the registration action. The testing program and labeling program are reviewed by the PM while the data portion is routed for scientific review to the appropriate discipline. On completion of the scientific review, the PM receives a written analysis of the data. If the data is found to be acceptable, an EUP is issued. If not, the EUP request is rejected and the PM then notifies the applicant in writing of the deficiencies before the EUP request can be resubmitted. The file is then updated in the tracking system to reflect the latest status and the registration jacket is stored in the file room.

5(c). Small Entity Flexibility

DRAFT FOR PUBLIC COMMENT

January 22, 2003

The Agency recognizes that many small businesses are involved in research and development activities with pesticides. In setting forth the notification requirements, EPA has sought to minimize the regulatory burden on research and development. Toward this end, the Agency has identified the minimum amount of data to be submitted to permit a scientific assessment of the proposed research. Much of this information already would be available to the respondent as part of the normal information developed during the research and development stage. These data requirements are flexible and may be adjusted as appropriate to the specific product under review. As an alternative to submitting a Notification, an applicant may apply for, and obtain an EUP before conducting a field test with a pesticide. Because the notification requirements have been designed from the outset to minimize the burden on respondents, as a result, there are no special measures taken for small businesses since already the burden is considered to be at a minimal level.

5(d). Collection Schedule

Not applicable. This activity is conducted only when an EUP request is made.

6. Estimating the Burden and Cost of the Collection

6(a). Estimating the Respondent Burden

Based on the respondent activities identified in section 3(b)(ii) above, the burden hours exhibited on the Master Table in section 6(d) were developed to represent a typical respondent to the notification and containment record-keeping requirements. Respondent burden hours are estimated at 10.10 hours per respondent at a cost of \$817.30. Based on the reduced number of applications received since the implementation of FQPA, specifically 1997 and 1998 fiscal years, the anticipated number of respondents for the 1999 fiscal year is 75. The total respondent burden is estimated to be 757.5 hours.

6(b). Estimating Respondent Costs

As stated above, the number of annual estimated respondents (applicants) is 75, with each spending approximately 10.10 hours responding. This total burden is estimated to cost \$64,950.00.

ANNUAL RESPONDENT BURDEN/COST ESTIMATES

Burden Hours (per year)	TOTAL			COLLECTION ACTIVITIES	
	Mgt. \$130/hr.	Tech. \$88/hr.	Cler. \$40/hr.	Hours	Costs
Read regulations	0.5	0.5	0.0	1.00	\$109.00

DRAFT FOR PUBLIC COMMENT

January 22, 2003

Plan activities	0.0	1.0	0.0	1.00	\$88.00
Create information	0.0	2.0	0.0	2.00	\$176.00
Gather information	0.0	2.5	0.0	2.50	\$264.00
Compile and review	0.0	2.0	0.0	2.00	\$176.00
Complete paperwork	0.1	0.5	0.0	0.60	\$57.00
Store/maintain data	0.0	0.0	1.0	1.00	\$40.00
TOTAL	0.60	8.50	1.00	10.10	\$910.00

ANNUAL BURDEN: 10.10 Total Hours x 75 Respondents = 757.50 Hours

ANNUAL COSTS

(a) Management: 0.6 hours x \$130 x 75 Respondents	\$5,850.00
(b) Technical: 8.50 hours x \$88 x 75 Respondents	\$56,100.00
(c) Clerical: 1.00 hours x \$40 x 75 respondents	<u>\$3,000.00</u>
Total	\$64,950.00

6(c). Estimating Agency Burden and Costs

ANNUAL AGENCY BURDEN/COST ESTIMATES

Burden Hours (per year)	TOTAL			COLLECTION ACTIVITIES	
	Mgt. \$96/hr.	Tech. \$70/hr	Cler. \$33/hr	Hours	Costs
Review submitted application package	0.0	2.0	0.0	2.00	\$140
Record submission	0.0	1.0	0.0	1.00	\$70
Analyze submission	1.0	8.0	0.0	9.00	\$656
File submission	0.0	2.0	1.0	3.00	\$173
TOTAL	1.0	13.00	1.00	15.00	\$1,039

ANNUAL BURDEN: 15 Total Hours x 75 Applicants = 1,125 Hours

ANNUAL COSTS

(a) Management: 1.0 hours x \$96 x 75 applicants	\$ 7,200.00
(b) Technical: 13.0 hours x \$70 x 75 applicants	\$68,250.00
(c) Clerical: 1.0 hours x \$33 x 75 applicants	<u>\$2,475.00</u>
Total	\$77,925.00

DRAFT FOR PUBLIC COMMENT

January 22, 2003

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.6(d). Bottom Line Hours And Costs / Master Table

MASTER TABLE

	TOTAL	
	Hours	Costs
Respondent Burden/Cost Estimates:	757.50	\$64,950.00
Agency Burden/Cost Estimates:	1,125	\$77,925.00

6(e). Reasons For Changes In Burden

The change in respondent burden hours, from 1,262.50 to 757.50 hours per year, is a result of the estimated reduction in the number of annual respondents, from 125 to 75. The change in annual respondent cost is a result of the estimated increase in hourly rates.

6(f). Burden Statement

The annual "respondent" (applicant) burden for the Application for Experimental Use Permit (EUP) to Ship and Use a Pesticide for Experimental Purposes Only program is estimated to average 10.10 hours per application. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information or forms to this address. The requested information should be

DRAFT FOR PUBLIC COMMENT

January 22, 2003

submitted in accordance with the instructions in the Federal Register Notice seeking comment on this ICR. Please reference this document by the OMB Control No. 2070-0040 in all correspondence.